DEREK J. MEYER (No. 278346)
LEONARDMEYER LLP
5900 Wilshire Boulevard, Suite 500
Los Angeles, CA 90036
(310) 220-0331
rmeyer@leonardmeyerllp.com

Attorney for Plaintiff

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE SOUTHERN DISTRICT OF CALIFORNIA

SAN DIEGO DIVISION

IONIS PHARMACEUTICALS, INC., a Corporation,

Plaintiff,

v.

ONCOGENEX TECHNOLOGIES, INC., a Corporation,

Defendant.

Case No. '16CV0016 JAH RBB

COMPLAINT

DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiff Ionis Pharmaceuticals, Inc. ("Ionis"), by and through its attorneys, states as follows for its Complaint against Defendant OncoGenex Technologies, Inc. ("OGX").

OVERVIEW OF ACTION

1. Ionis is a pharmaceutical company that discovered a cancer drug with OGX. Ionis brings this lawsuit to recover its 30% contractual share of "Non-Royalty Revenues" received by OGX in connection with two agreements OGX entered with Teva Pharmaceuticals Industries Ltd. ("Teva") relating to the drug. To date, Teva has paid OGX $23.2 million pursuant to such agreements and provided substantial other value to OGX falling within the definition of Non-Royalty

Revenue. OGX has wrongfully refused to pay Ionis its contractual share of Non-Royalty Revenue, including its share of the above-referenced valuable in-kind assets that OGX received from Teva. As set forth in greater detail below, Ionis seeks damages in the amount of at least $10,000,000, prejudgment interest, and declaratory relief.

PARTIES

2. Plaintiff Ionis (formerly known as Isis Pharmaceutical, Inc. until December 2015) is a Delaware corporation with its principal place of business located in Carlsbad, California.

3. Defendant OncoGenex Technologies, Inc. is a Canadian corporation with its principal place of business located in Vancouver, British Columbia, Canada.

JURISDICTION AND VENUE

4. Jurisdiction exists pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the Plaintiff and Defendant and the amount in controversy exceeds $75,000, exclusive of interest and costs.

5. Venue in this district is proper pursuant to 28 U.S.C. §1391(b)(2).

GENERAL ALLEGATIONS COMMON TO ALL COUNTS

Ionis

6. Together, Ionis and OGX, discovered an antisense cancer drug known as OGX-011 (also known as custirsen) pursuant to a 2001 discovery and collaboration agreement. After many years of successful collaboration beginning in 2001, Ionis and OGX advanced OGX-011 through the various stages of pre-clinical and early clinical development.

7. By way of background, most drugs produced by the pharmaceutical and biotechnology industries, such as small molecules (e.g., Lipitor) or protein based therapies (e.g., Enbrel) are designed to bind to and interfere with the function of disease-causing proteins.

8. OGX-011, using antisense technology, differs from those pharmaceutical approaches. Antisense compounds bind to specific mRNAs that encode disease causing proteins, and can work by a variety of mechanisms.

9. An antisense compound is typically a short, single-stranded DNA polymer, often called an "oligonucleotide," that is comprised of individual units called nucleotides.

10. OGX-011, as an anti-cancer antisense drug, was designed to inhibit the production of the protein, clusterin. Clusterin acts as a cell-survival protein that is over-expressed in response to tumor killing strategies, such as chemotherapy, hormone ablation and radiation therapy. Inhibiting clusterin is intended to enhance the effects of drug therapies in the treatment of certain hard-to-treat cancers.

11. Ionis's research and development efforts have also yielded a number of transformative discoveries. These include not only the discovery of specific drug compounds, but more fundamental discoveries regarding the underlying chemistry of antisense oligonucleotides, the mechanisms by which oligonucleotides can be exploited to generate a therapeutic benefit, methods of administering antisense oligonucleotides, and an industry-leading, commercial quality manufacturing process.

12. These discoveries have been fundamental to the ability of antisense oligonucleotides to make the leap from the laboratory to human treatment. In essence, through significant investment and scientific breakthroughs, Ionis has optimized the way to design antisense drugs to maximize the likelihood of success as human therapeutics.

13. Ionis's advances were only achieved through extraordinary effort at tremendous expense. During its over 25 year history, Ionis has made enormous investments of time, money and effort researching and developing antisense technology, and its monetary investment exceeds $3 billion to date in order to convert antisense into a viable and proven platform for human therapeutics.

Ionis is a highly sought after collaboration partner. In particular, Ionis is the only company to have successfully received FDA approval for an antisense drug.

14. OGX-011 incorporates Ionis' optimized and patented antisense drug technology.

OGX

15. As stated on its webpage, OGX is a biopharmaceutical company committed to the development and commercialization of new therapies that address treatment resistance in cancer patients.

16. OGX was established in May 2000 as a spin out from the Prostate Centre at Vancouver General Hospital and the University of British Columbia. It was co-founded by Dr. Martin Gleave, the Company's scientific founder and Chief Scientific Advisor, and Scott Cormack, OGX's President and CEO, initially to develop and commercialize OGX-011.

17. OGX-011 is the most advanced drug in OGX's pipeline. The drug is currently in Phase III clinical development as a treatment in men with metastatic castrate-resistant prostate cancer (the "AFFINITY" study) and in patients with advanced, unresectable non-small cell lung cancer (the "ENSPIRIT" study).

18. In addition to OGX-011, OGX has other drugs in its pipeline. For example, Apatorsen is in Phase II clinical development and another drug OGX-225 is currently in preclinical development. Both are antisense cancer drugs that also incorporate Ionis' patented antisense platform technology.

The Parties' November 16, 2001 Collaboration and Co-Development Agreement

19. On November 16, 2001, Ionis and OGX entered a Collaboration and Co-Development Agreement ("Collaboration Agreement") to co-develop OGX-011 until the completion of the parties' project plan, at which time the parties contemplated the introduction of another commercial partner.

20. OGX was interested in pursuing antisense drugs against the target, clusterin. As such, OGX approached Ionis to apply Ionis' proprietary antisense technology to design antisense drugs targeting clusterin. This resulted in OGX-011.

21. After designing and discovering the drug, under the Collaboration Agreement, Ionis conducted preclinical toxicology and pharmacokinetic studies of OGX-011 and manufactured OGX-011 for preclinical and Phase I/II studies.

22. OGX was responsible for performing the Phase I/II clinical trials to assess the safety and efficacy of OGX-011, with Ionis responsible for 35% of the development costs.

23. At the time of the Collaboration Agreement, Phase I trials with OGX-011 had not yet commenced. Before the restructuring of this Collaboration Agreement in 2008 (discussed below), Ionis contributed over $8 million to support the research and development of OGX-011.

24. As noted by Scott D. Cormack, OGX's President and CEO, at the time of Collaboration Agreement, "We believe the combined experience of OncoGenex in cancer biology and clinical trials together with [Ionis's] development experience and advances in second-generation antisense chemistry will contribute tremendously to the potential of this promising new cancer compound."

25. In the ensuing years, the parties then collaborated to jointly develop OGX-011 with promising advances.

The Parties' July 2, 2008 Agreement

26. In 2008, the parties agreed to restructure their relationship. As part of the 2008 restructuring, Ionis granted OGX the exclusive right to develop and commercialize OGX-011 and access to Ionis's valuable product and platform patents needed to commercialize OGX-011.

27. In exchange for these valuable rights, OGX agreed to make substantial payments to Ionis including a share of revenues received by OGX relating to OGX-011.

28. Thus, on or about July 2, 2008, the parties entered into an "Amended and Restated License Agreement" (the "Restated Agreement")[1]. Pursuant to the Restated Agreement, the parties terminated the prior 2001 collaboration agreement regarding OGX-011.

29. Further, pursuant to the restructuring:

a. OGX increased its economic interest in the drug,

b. OGX gained unilateral control over the development of the drug,

c. OGX gained unilateral control over picking a commercial partner and structuring the partnering transaction for the drug,

d. OGX received Ionis's ownership in the fundamental patents covering the drug,

e. OGX received a license to practice Ionis's patented antisense technology platform that was incorporated into the drug,

f. Ionis was no longer required to pay 35% of the development costs for the drug, and is entitled to receive modest royalties, and

g. Ionis is entitled to 30% of all Non-Royalty Revenue OGX receives in connection with the drug.

[1] Each of the agreements cited in this Complaint contain proprietary, confidential business sensitive information. As a result, and out of an abundance of caution, those agreements are not attached here. Both parties have possession of those agreements and they can be filed under seal upon entry of a protective order.

30. In an OGX press release dated July 3, 2008, under the headline "OncoGenex Increases Economic Interest in Lead Cancer Drug OGX-011," OGX's CEO, Scott Cormack stated:

> This amendment allows us to increase our economic interest in OGX-011 as we advance the development of OGX-011 while also increasing our flexibility to further develop this product candidate. . . In addition, we believe this new arrangement facilitates future partnering discussions since potential development and commercialization partners need only deal with one party.

31. Ionis provided significant benefits to OGX under the Amended and Restated Agreement.

32. The agreement provided OGX with Ionis's ownership interest in the fundamental patents covering OGX-011, and a worldwide license, with a right to grant sublicenses, under "Isis Core Technology," "Isis Core Technology Patents, "Isis Manufacturing Technology," and "Isis Manufacturing Patents."

33. Without such an assignment and license, neither OGX-011 nor any related "Product" as defined in the agreement could be commercialized. In addition, Ionis agreed not to compete with OGX using any antisense drug targeting clusterin.

34. These rights were and remain extremely valuable to OGX, as well as any OGX commercialization partner.

35. In recognition of Ionis's work in jointly discovering and developing OGX-011 and these valuable rights, the Amended and Restated Agreement therefore contemplated significant payments to Ionis.

36. Further, by way of additional background, it is worth noting that drug development collaborations typically require the developing partner (here OGX) to pay the licensing partner (here Ionis) significant milestone payments in the millions of dollars as the drug advances through development and commercialization.

37. For example, most partnering transactions require significant payments to the licensor upon the start of Phase 3 studies. Ionis could have sought such stand-alone milestone payments from OGX. This typical structure would have required OGX to make payments to Ionis if OGX achieved a development threshold even if it had not received any monies in connection with that achievement from a third-party commercial partner.

38. Here, however, Ionis collaboratively took the view that Ionis would get paid when OGX got paid. As such, the agreement was structured such that if OGX received consideration in connection with OGX-011, Ionis would be entitled to share in such consideration.

39. Consistent with this approach, Ionis and OGX intentionally defined revenue very broadly to reflect the mutual intent that Ionis should receive value when OGX receives value.

The December 20, 2009 OGX/Teva Agreement

40. On December 20, 2009, OGX and Teva, a large pharmaceutical company based in Israel, entered a Collaboration and License Agreement ("Teva Collaboration Agreement").

41. The purpose of that agreement was to further develop and commercialize OGX-011.

42. Pursuant to the agreement, Teva was granted the exclusive worldwide right and license to develop and commercialize any products containing OGX-011 and related compounds. OGX retained an option to co-promote OGX-011 in the United States and Canada.

43. Teva made upfront payments to OGX in the aggregate amount of $50 million, and agreed to make payments of up to $370 million upon the achievement of developmental and commercial milestones and royalties at percentage rates ranging from the mid-teens to mid-twenties on net sales, depending on aggregate annual net sales of licensed drugs. Teva also acquired $10 million of OGX common stock at a premium under a separate Stock Purchase Agreement.

44. Except as noted below, the agreement required Teva to fund all expenses under the Teva Collaboration Agreement including the SYNERGY, AFFINITY and ENSPIRIT trials being conducted under the amended clinical development plan OGX developed with Teva.

45. The agreement required OGX to spend $30 million in direct and indirect development costs such as time incurred by OGX personnel for the benefit of the custirsen development plan, with such contribution to be funded by the upfront payment provided by Teva.

The Parties' Amendment to Restated Agreement

46. During the negotiation between OGX and Teva, Teva required OGX to obtain certain concessions from Ionis.

47. To support the long-term prospects of the drug and in the spirit of cooperation, Ionis agreed to accommodate OGX's request and amend the 2008 restructuring agreement.

48. Section 2.13 of the Amendment adopted the following definition of Revenue – a minor revision to its prior definition – for purposes of the parties' Amended and Restated Agreement:

> "'Revenue' means all revenues, receipts, monies, and the fair market value of all other consideration received by OncoGenex relating to the sale, license or any other commercial transaction involving OGX-011 and/or the Product, with the exception of the following: (1) any consideration received for the reimbursement for research and development activities and (2) any consideration received for the fair market value of any sale of equity or quasi-equity securities, including without limitation, common shares and preferred shares."

49. The Amended and Restated Agreement, in turn, defines "Non-Royalty Revenue" as "all Revenue received by OncoGenex with the exception of Royalty Revenue and OncoGenex Direct Sales."

December 2014 Termination Agreement between OGX and Teva

50. In December 2014, after a Phase 3 study of OGX-011 failed to reach its primary endpoint, OGX and Teva reached an initial agreement to terminate their collaboration and return the rights to the drug to OGX

51. Thus, on or about December 29, 2014, Teva and OGX entered an agreement to terminate their Collaboration and License Agreement (the "December 2014 Termination Agreement") pursuant to which OGX and Teva agreed to enter into a second agreement within 20 days to terminate the 2009 Teva Collaboration Agreement.

52. The December 2014 Termination Agreement covered in detail many significant issues regarding the wind-down of the OGX-Teva relationship. Section 3 of the agreement stated: "On a date to be determined, but no later than 20 business days following execution of the Final Settlement Agreement (the 'Closing Date'), Teva will pay OGX $27 million (the 'Settlement Amount') and the Collaboration and License Agreement shall be terminated."

53. The "Settlement Amount" is the source of the $23.2 million payment at issue (i.e. the $27 million minus certain holdbacks by Teva). OGX also received other Non-Royalty Revenue from Teva, including bulk drug substances and drug product with significant value of which Ionis is entitled to its contractual share of such value as Non-Royalty Revenue.

54. As reported in OGX's contemporaneous Form 8-K filing with the U.S. Securities and Exchange Commission, the December 2014 Termination Agreement ensured that OGX would "regain rights to custirsen, an investigational compound currently being evaluated in Phase 3 clinical development as a treatment for prostate and lung cancers." Further, the companies agreed to "a $27 million payment from Teva [to OGX], which will be reduced by the amount of third-party expenses incurred and paid by Teva" that related to certain studies.

55. The December 2014 Termination Agreement, attached as an exhibit to OGX's December 31, 2014 Form 10-K Annual Report filing, specifically defines the $27 million payment as a "Settlement Amount."

56. Teva accounted for this settlement payment as an expense in 2014, labeling the payment "costs associated with cancellation of R&D projects."

April 24, 2015 Termination Agreement (OGX and Teva)

57. Perhaps recognizing its liability to Ionis, and in a futile attempt to circumnavigate the parties' Restated Agreement, as amended, OGX subsequently restyled the language of the December 2014 Termination Agreement with Teva, which ultimately resulted in those parties' April 24, 2015 Termination Agreement (the "April 2015 Termination Agreement"). In that version, the "Settlement Amount" is misleadingly described as "advanced reimbursement for certain continuing research and development activities."

58. Notwithstanding this effort, the April 2015 Termination Agreement also expressly states that Teva agreed to pay such amounts to OGX "in consideration of the releases and other agreements" set forth in the April 2015 Termination Agreement.

59. Some time after April 24, 2015, Teva paid OGX approximately $23.2 million dollars, pursuant to the April 2015 Termination Agreement.

60. There is no term in either Teva's and OGX's December 2014 or April 2015 Termination Agreements that *requires* OGX to (1) spend the repayment on research and development activities relating to OGX-011, (2) provide Teva progress reports or the results of the development activities, (3) permit Teva to audit OGX's books, or (4) refund the monies to Teva if OGX does not complete such activities. The conditions described in clauses (1) through (4) are customary conditions found in true reimbursement arrangements.

61. Further, per OGX's own public statements, the monies received from Teva were even used for non-OGX-011 related products, such as Borealis-2, Spruce, and Rainier, and not for OGX-011 related expenses.

62. Despite the label OGX has attempted to place on the Teva payment, for these reasons and additional reasons, the $23.2 million payment is Non-Royalty Revenue as defined in Ionis and OGX's Restated Agreement.

Ionis Claims Its Share of Settlement Amount From OGX

63. Thereafter, on May 5, 2015, Ionis notified OGX of its claim to a portion of the "Settlement Amount," as Non-Royalty Revenue under the parties' July 2, 2008 Restated Agreement, as amended.

64. OGX refused at that time, and continues to refuse, to recognize its payment obligations to Ionis pursuant to the parties' Restated Agreement. To date, despite numerous demands from Ionis for its contractual portion of the $23.2 million payment from Teva to OGX, OGX has not paid a single dollar.

65. OGX, by its own public statements, continues to use that payment for development of various of its other products, not only depriving Ionis of its fair share of the monies OGX received from Teva, but also making Ionis *de facto* pay for the continued development of OGX-011 and other products for which it receives no benefit.

LEGAL CLAIMS

COUNT I
BREACH OF CONTRACT

66. Plaintiff incorporates by reference paragraphs 1 through 65 as if fully set forth herein.

67. On or about July 2, 2008, the parties entered into a valid and enforceable contract, supported by good and valuable consideration in the form of their "Amended and Restated License Agreement."

68. OGX has breached the Restated Agreement as set forth above by, *inter alia*, refusing to pay Ionis the contractually obligated amount of the Non-Royalty Revenue funds received by OGX from Teva, pursuant to those parties' December 2014 and/or April 2015 Termination Agreements.

69. As a direct and proximate cause of OGX's breach of its contract with Ionis, Ionis has suffered and continues to suffer substantial monetary damages.

70. Ionis has satisfied any and all conditions precedent to assert this claim and has fulfilled all of its obligations pursuant to the parties' agreement.

WHEREFORE, Plaintiff, Ionis, by and through his undersigned counsel, respectfully prays for the entry of judgment in his favor and against Defendant, OGX, on Count I of this Complaint, in an amount in excess of $75,000, plus all allowable interest, and for all such other and further relief as is appropriate and legally allowable under the circumstances.

COUNT II

DECLARATORY RELIEF

71. Plaintiff incorporates by reference paragraphs 1 through 65 as if fully set forth herein.

72. Pursuant to Section 12.2 of the parties July 2, 2008 Restated Agreement, as amended December 18, 2009, if OGX were to breach OGX's "obligation to make a payment to [Ionis] under Article 6," which includes the Non-Royalty Revenue at issue in this lawsuit, Ionis is required to provide OGX a 30-day notice and opportunity to cure that breach.

73. Ionis provided such notice, at the latest, on November 6, 2015.

74. To date, OGX has failed to cure its material breach and has failed to make a payment to Ionis, pursuant to Article 6 of the Restated Agreement.

75. Pursuant to that same agreement, as amended December 18, 2009, Article 9 provides that Ionis "will have the right to terminate this Agreement and/or any licenses granted by it hereunder solely in accordance with Article 12."

76. Because of OGX's breach and failure to cure under Article 12, Ionis now seeks a declaration, as a matter of law, that it can exercise its right to terminate the Restated Agreement and any and all licenses granted to OGX through the Restated Agreement.

WHEREFORE, Plaintiff, Ionis, by and through its undersigned counsel, respectfully prays for the entry of judgment in his favor and against Defendant, OGX, on Count II of this Complaint, and for a declaration of its rights under the Restated Agreement – namely its right to terminate the Restated Agreement and any and all licenses granted to OGX through the Restated Agreement, and for all such other and further relief as is appropriate and legally allowable under the circumstances.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff by and through its undersigned counsel, respectfully prays for the entry of judgment in its favor and against Defendant as follows:

1. For an award of compensatory damages in an amount to be ascertained at trial;
2. For incidental and consequential damages to be ascertained at trial;
3. For all available pre-judgment and post judgment interest;
4. For costs of suit incurred;
5. For its reasonable attorneys' fees;

6. For a declaration of Plaintiff's right to terminate the Restated Agreement, including any and all licenses granted to OGX, through the Restated Agreement; and,

7. For any and all other relief the Court deems just and reasonable.

Dated: January 5, 2016

Respectfully submitted,

By: /s/ Derek J. Meyer

DEREK J. MEYER
LEONARDMEYER LLP
5900 Wilshire Boulevard, Suite 500
Los Angeles, CA 90036
(310) 220-0331
rmeyer@leonardmeyerllp.com

Attorney for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff respectfully requests a jury trial on all issues triable thereby.

Dated: January 5, 2016

Respectfully submitted,

By: /s/ Derek J. Meyer

DEREK J. MEYER
LEONARDMEYER LLP
5900 Wilshire Boulevard, Suite 500
Los Angeles, CA 90036
(310) 220-0331
rmeyer@leonardmeyerllp.com

Attorney for Plaintiff